

IMPACT OF DIABETIC COMPLICATIONS ON HEALTH-RELATED QUALITY OF LIFE OF PATIENTS WITH TYPE 2 DIABETES MELLITUS AT A TERTIARY CARE TEACHING HOSPITAL IN INDIA

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Abstract

Background: Long-term diabetic complications have a great negative impact on the health-related quality of life of patients with type 2 diabetes mellitus. The study aimed to describe the influence of diabetic complications on HRQoL in patients with type 2 diabetes mellitus.

Materials and Methods: A hospital-based cross-sectional study was conducted at a tertiary teaching hospital in India. The study included all patients with type 2 diabetes mellitus above 18 years of age and currently on medication. The study was conducted upon approval from the Institutional Ethics Committee (IEC) and informed consent was taken from all the participants before including them in this study. The European Quality of Life questionnaire (EQ-5D-5L) is used in this study to assess the patient's health-related quality of life.

Results: A total of 200 patients participated in this study. Majority of the study participants, 40.5% were adherent to the medication prescribed by the physician and 59.5% were non-adherent to the medication. Hypertension is found to be the most common diabetic comorbidity and complication and CAD, Stroke, and Nephropathy are less frequent diabetic complications but are found to have a greater impact on HRQoL reduction. The mean EQ VAS score was 78.25 ± 14.60 and the mean EQ Index score was 0.8574 ± 0.1432 . Mean EQ VAS scores for males and females were 80.3365 ± 14.0779 and 75.9896 ± 14.8965 respectively. The mean EQ Index scores for males and females were 0.8657 ± 0.1458 and 0.8483 ± 0.1405 respectively. The mean scores of the HRQoL (both EQ Index and EQ VAS) were found to decrease with the increase in number of diabetic complications.

Conclusion: Our study found that patients with type 2 diabetes mellitus have poor health-related quality of life. Non-adherence to medication and the presence of diabetic complications further deteriorate the quality of life of the patients.

Key Words: Diabetic Complications, Health-related Quality of Life (HRQoL), EQ-5D-5L, Type 2 Diabetes Mellitus.

Introduction

Type 2 Diabetes Mellitus (T2DM) is regarded as the leading cause of disabilities and death worldwide due to an alarming rise in its cases and evolved as a major challenge to the healthcare system in developing countries like India.^(1,2) It is a chronic metabolic disease that involves serious complications that affect the health-related quality of the patients and lead to morbidity, disabilities, mortality, and increased treatment costs.⁽³⁾ Untreated and uncontrolled T2DM causes chronic complications such as macrovascular complications (coronary artery disease (CAD), peripheral vascular disease (PVD), stroke), microvascular complications (retinopathy, neuropathy, and nephropathy), and non-vascular diabetic complications (diabetic foot ulcers, hypoglycemia, diabetic ketoacidosis, and hyperosmolar hyperglycemic state).⁽⁴⁻⁸⁾ These chronic diabetic complications affect the patient's health-related quality of life and these complications along with comorbidities decrease the patient's productivity and compromise the life expectancy.^(9,10)

The World Health Organisation (WHO) defined the quality of life as "an individual's perception of their position of life in the context of their culture and values, and concerning their standards, concerns, expectations, and goals."⁽¹¹⁻¹³⁾ Whereas the health researchers narrowed this concept and defined the Health-related Quality of Life (HRQoL) as, "an individual's perception of the extent to how disease, disability, or disorder affect their physical, emotional, and social status."⁽¹⁴⁾ There are various tools available for measuring the patient's HRQoL. These include WHO-BREF⁽¹⁵⁾, SF 36^(16,17), Health Utility Index (HUI)^(18,19), and EQ-5D etc. EQ-5D is one of the Multi-Attribute Utility Instruments (MAU), which is a standardized measure of health status. It is developed by EuroQol Group to provide a simple and generic measure of HRQoL for use in clinical and economic appraisal.⁽²⁰⁾

The ultimate goal of treating T2DM is to increase the quality of life of the patient. This can be achieved only through individualized optimal drug therapy. The optimal treatment guidelines are prepared for individualized patients by measuring their health status and understanding the complications and comorbidities in each patient.^(21,22) Adherence to the medication prescribed by the physician is also known to affect the health of the patient. Many researchers have reported that treatment non-adherence leads to the development of chronic complications in diabetic patients which in turn increase the disease burden and decrease the quality of life of the patient.⁽²³⁾

Materials and Methods

A cross-sectional study was conducted from July 2022 to December 2022 at the Konaseema Institute of Medical Sciences & Research Foundation (KIMS) teaching hospital, Amalapuram, India.

The study included all male and female patients with type 2 diabetes mellitus above 18 years of age. All the participants included in the study must be diagnosed with T2DM for at least one year and should be on oral hypoglycemic therapy. The study was approved by the KIMS Institutional Ethics Committee (IEC) and informed consent was taken from all the participants before including them in this study. All the participants were asked to complete

the standard questionnaire and the patient data was collected through the patient's case report form (CRF).

The European Quality of Life questionnaire (EQ-5D-5L) is used in this study to assess the patient's health-related quality of life.⁽²⁴⁾ The EQ-5D-5L scale consists of a descriptive system and a Visual Analogue Scale (VAS). The EQ-5D-5L descriptive system comprises five dimensions: Mobility, Self-care, Usual Activities, Pain/Discomfort, and Anxiety/Depression. Each dimension has five levels: No problems, Slight problems, Moderate problems, Severe problems, and Extreme problems. The participant is asked to answer each question by ticking the box against the most appropriate answer at each level. Then a 1-digit number (1 to 5) obtained by each dimension is combined to form a 5-digit number (eg. 11111), which describes the health state of the participant. An EQ Visual Analogue Scale (EQ VAS) self-rated vertical health scale from 0 to 100, where 0 represents "the worst health you can imagine" and 100 represents "the best health you can imagine".⁽²⁵⁾ All the participants are allowed to mark "X" on the scale to indicate their current health status – "how your health is TODAY". The scoring of this scale is done as per the standard guidelines and EQ index scores were calculated using the EQ-index value sets for India from the previous studies conducted by research scholars.⁽²⁶⁾

All the patient's socio-demographic data (age, sex, social habits, family history, etc.), duration of diabetes, comorbidities, chronic diabetic complications, HbA1c levels, self-reported adherence to diabetic medication ('yes' or 'no'), and quality of life (EQ-5D-5L score) was collected and entered into MS Excel Spreadsheet and analyzed for descriptive statistics (Frequency (N) Mean, and Percentage (%)). The results are obtained in the form of tables, figures, and charts/graphs.

Results:

A total of 200 patients participated in this study. Out of these, males were 112 (56%) and females were 88 (44%). The mean age of the patients was found to be 53.73 ± 12.0 years. The socio-demographic data of the study participants showed that most of the diabetic patients reported a family history of T2DM, stressful lifestyle, lack of exercise or physical activity, and altered psychoemotional status. Table 1 depicts the socio-demographic data of patients.

Table 1. Characteristics of Type 2 Diabetes Patients (N=200).

Characteristics	N = 200
Age (yr) (Mean \pm SD)	53.73 \pm 12.0
Gender (%)	Male 112 (56 %) Female 88 (44 %)
Marital Status (%)	Married (93 %)
Monthly Income INR (Mean \pm SD)	25800 \pm 6500
Duration of Diabetes (yr) (Mean \pm SD)	8.07 \pm 6.75
Family History of Type 2 Diabetes N (%)	137 (68.5%)
No Exercise (Physical activity) N (%)	140 (70 %)
Obesity N (%)	64 (32 %)
Stressful Lifestyle N (%)	116 (58 %)
Smoking N (%)	40 (20 %)
Alcohol Intake N (%)	36 (18 %)

Decreased Sleep N (%)	90 (45 %)
Frequent Urination N (%)	80 (40 %)
Diabetes Controlled N (%)	129 (64.5 %)
Uncontrolled Diabetes N (%)	71 (35.5 %)
Adherence to Medication	Adherent 81 (40.5 %) Non-Adherent 119 (59.5 %)
No Comorbidity N (%)	94 (47 %)
With Comorbidity N (%)	106 (53%)
No. of antidiabetic Drugs (OHA)	
1	75 (37.5 %)
2	84 (42%)
≥3	26 (13 %)
OHA + Insulin	11 (5.5 %)
Insulin Therapy	4 (2%)
EQ Index Score (Mean ± SD)	0.8574 ± 0.1432
EQ VAS Score (Mean ± SD)	78.25 ± 14.60

Majority of the study participants,40.5% were adherent to the medication prescribed by the physician and 59.5% were non-adherent to the medication. The main reasons for non-adherence in these patients were identified to be Forgetfulness (38.27%), Lack of Awareness (16.05%), Lack of Financial Resources (17.28%), and Negligence (28.40%).Most of the younger diabetic patients (aged 25 to 45 years), recently diagnosed with type 2 diabetes (duration of diabetes 1 to 5 years) neglect to take the prescribed drugs. The study results showed that hypertension is the most common diabetic comorbidity and complication followed by Retinopathy, Peripheral Neuropathy, and Peripheral Vascular Disease.⁽²⁷⁾The summary of diabetic complications found in the study sample is given in Table 2.

Table 2: Diabetic Complications in the study participants (N=200).

Self-reported Diabetic Complications	N (%)
Hypertension	122 (61)
Cerebrovascular Disease (Stroke)	46 (23)
Cardiovascular Disease (CAD)	28 (14)
Retinopathy	108 (54)
Nephropathy	30 (15)
Peripheral Neuropathy	105 (52.5)
Peripheral Vascular Disease (PVD)	98 (49)
Diabetic Foot Ulcers	48 (24)
Weight Loss	54 (27)
None	9 (4.5)

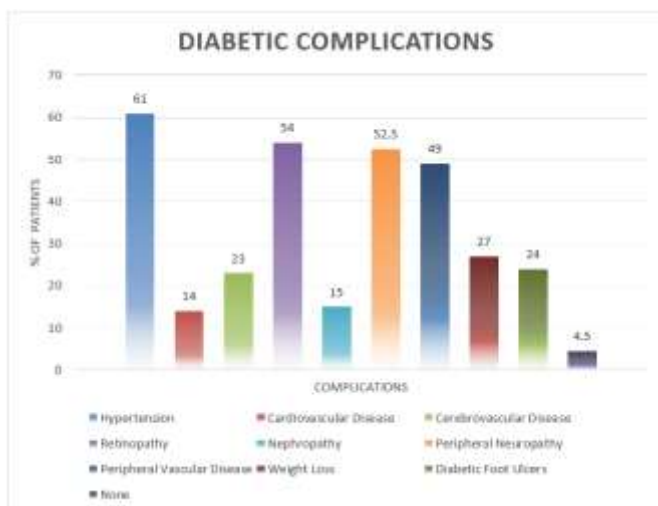


Figure 1: Diabetic Complications.

The quality of life of the study participants was observed using the EQ-5D-5L questionnaire. The EQ index score and EQ VAS score were taken as the index of patient quality of life. Table 3 shows the distribution of the percent of DM patients reporting EQ 5D levels 1 to 5 by dimensions and age group. Mobility, self-care, usual activities, pain/discomfort, and anxiety/depression were most affected in the age group 66 – 75 years with 38.89%, 77.55%, 50%, 19.44%, and 33.89% respectively.

Table 3: Frequency and Percentage Distributions of EQ-5D-5L dimensions by age group (N=200).

DIMENSION	AGE GROUP				
	25 – 35 N (%)	36 – 45 N (%)	46 – 55 N (%)	56 – 65 N (%)	66 – 75 N (%)
Mobility					
Level 1	13 (72.22)	16 (51.61)	38 (57.58)	22 (44.9)	14 (38.89)
Level 2	4 (22.22)	13 (41.94)	20 (30.3)	17 (34.69)	13 (36.11)
Level 3	0 (0)	2 (6.45)	7 (10.61)	9 (18.37)	9 (25.0)
Level 4	1 (5.56)	0 (0)	1 (1.52)	1 (2.04)	0 (0)
Level 5	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Self-care					
Level 1	18 (100)	28 (90.32)	56 (84.85)	38 (77.55)	30 (83.33)
Level 2	0 (0)	3 (9.68)	10 (15.15)	11 (22.45)	6 (16.67)
Level 3	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Level 4	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Level 5	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Usual-Activities					
Level 1	16 (88.89)	21 (67.74)	40 (60.61)	30 (61.22)	18 (50)
Level 2	2(11.11)	10 (32.26)	22 (33.33)	15 (30.61)	14 (38.89)
Level 3	0 (0)	0 (0)	4 (6.06)	4 (8.16)	3 (8.33)
Level 4	0 (0)	0 (0)	0 (0)	0 (0)	1 (2.78)
Level 5	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Pain/Discomfort					
Level 1	11 (61.11)	12 (38.71)	38 (57.58)	20 (40.82)	7 (19.44)
Level 2	5 (27.78)	13 (41.94)	17 (25.76)	17 (34.69)	17 (47.22)
Level 3	1 (5.56)	6 (19.35)	7 (10.61)	8 (16.33)	10 (27.78)
Level 4	1 (5.56)	0 (0)	4 (6.06)	3 (6.12)	2 (5.56)
Level 5	0 (0)	0 (0)	0 (0)	1 (2.04)	0 (0)
Anxiety/Depression					
Level 1	9 (50)	15 (48.39)	31 (46.97)	22 (44.9)	14 (33.89)
Level 2	6 (33.33)	9 (29.03)	25 (37.88)	19 (38.78)	12 (33.33)
Level 3	2 (11.11)	5 (16.13)	10 (15.15)	8 (16.33)	8 (22.22)
Level 4	1 (5.56)	2 (6.45)	0 (0)	0 (0)	2 (5.56)
Level 5	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The mean EQ VAS score was 78.25 ± 14.60 and the mean EQ Index score was 0.8574 ± 0.1432 . Mean EQ VAS scores for males and females were 80.3365 ± 14.0779 and 75.9896 ± 14.8965 respectively. The mean EQ Index scores for males and females were 0.8657 ± 0.1458 and 0.8483 ± 0.1405 respectively. The mean EQ VAS and Index scores distribution based on age group is given in Figures 2 and 3.

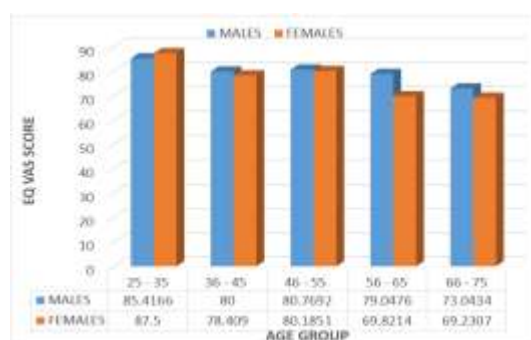


Figure 2: Age and Gender-wise Mean EQ VAS Scores of the study participants (N=200).

The distribution of study participants based on the number of complications reported that the majority of patients with type 2 diabetes mellitus had ≥ 4 complications 80 (40 %) and patients with no complications are least in number 9 (4.5 %). The mean EQ Index and VAS scores of the study participants were distributed based on the presence of the number of complications in each diabetic patient given in Table 4. The mean scores of the QoL (both EQ Index and EQ VAS) were found to decrease with the increase in number of diabetic complications. Figure 4 depicts the trends in the quality of life of the patients with increasing diabetic complications.

Table 3: MeanEQ-5D-5L Index and VAS values with and without Diabetic Complications.

No of Complications	N	EQ-5D-5L Index					EQ-5D-5L VAS				
		Mean \pm SD	Min	25%	75%	Max	Mean \pm SD	Min	25%	75%	Max
0	9	0.9206 \pm 0.1169	0.6410	0.9050	1.0000	1.0000	86.88 \pm 17.09	40	85	95	95
1	33	0.8902 \pm 0.1482	0.3400	0.8740	1.0000	1.0000	84.24 \pm 11.46	40	80	95	95
2	45	0.8580 \pm 0.1638	0.2540	0.8380	0.9840	1.0000	78.11 \pm 16.69	40	70	90	95
3	33	0.8679 \pm 0.1165	0.5480	0.8530	0.9340	1.0000	75.45 \pm 11.68	50	65	85	95
≥ 4	80	0.8121 \pm 0.1372	0.3090	0.7615	0.8990	1.0000	72.56 \pm 15.01	40	60	85	95

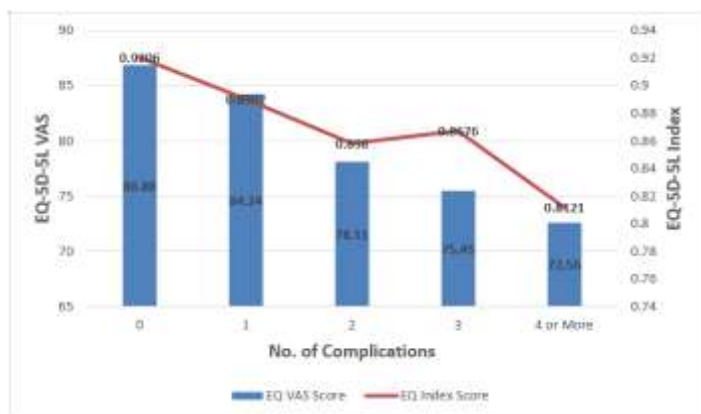


Figure 3: Trends of Mean EQ-5D-5L Index and VAS scores on increasing number of complications.

Discussion

The decrease in health-related quality of life (HRQoL) of type 2 diabetic patients was reported by various research scholars through their studies. The quality of life of the patients is measured using many standardized questionnaires, EQ-5D-5L is one among them. The validity and reliability of the EQ-5D-5L tool in measuring the health-related quality of life of type 2 diabetic patients among the Indian population was reported by the studies conducted by Sayah *et al.*⁽²⁷⁾ and Patel *et al.*⁽²⁸⁾

Our study results indicate that even a mild stage of diabetic complications can affect the quality of life of patients to a greater extent. The most commonly observed co-morbidity & complication in type 2 diabetic patients was hypertension (61%) which is similar to the studies conducted by Adam Lloyd *et al.*⁽²⁹⁾ Bharti N. Karelia *et al.*⁽³⁰⁾ and Kalpana Tiwari *et al.*⁽³¹⁾

The United Kingdom Prospective Diabetes Study (UKPDS) study results found that effective treatment of hypertension in type 2 diabetic patients showed a great impact on decreasing the risk of micro-and macro-vascular complications thereby increasing their HRQoL.^(32,33) Other commonly found diabetic complications in the Indian population were Retinopathy (54%), peripheral neuropathy (52.5%), and peripheral vascular disease (49%). The least commonly occurring diabetic complication was found to be nephropathy (15%) these results are very similar to the findings reported by Alex SM *et al.*⁽³⁴⁾ and Bharti *et al.*⁽³⁰⁾ However, a study conducted by Adam Lloyd *et al.*⁽²⁹⁾ reported Peripheral sensory neuropathy is a leading complication after hypertension. Our study reported that impaired vision in diabetic patients (Retinopathy) is associated with decreased HRQoL in about 54 % of patients which is similar to the study results reported by Hanninen J *et al.*⁽³⁵⁾ but our results are contrary to the findings reported by Lloyd *et al.*⁽²⁹⁾

Although CAD, Stroke, and Nephropathy are less frequent diabetic complications, they are found to have a greater impact on HRQoL reduction, and Retinopathy which is the most frequent diabetic complication shown to have a limited effect on decreasing the quality of life of type 2 diabetic patients, these results are also found to be compatible to the study results conducted by Tuyen Ba Pham *et al.*⁽³⁶⁾ and Lloyd *et al.*⁽²⁹⁾ Peripheral vascular disease (PVD) and Peripheral Neuropathy are also found to have a significant impact in the HRQoL reduction in the diabetic patients.

A self-reported medication adherence was taken from all the participants involved in this study. Most of the subjects 59.5% were non-adherent to the medications prescribed by the physician whereas 40.5% were adherent to the medications. The reasons for the non-adherence to medication among diabetic patients were also assessed. The main reasons for non-adherence were found to be forgetfulness 38.27% and Negligence 28.4%, which is contradicted by the study results reported by Farzana Saleh *et al.*⁽³⁷⁾ Negligence to medication is the main cause of non-adherence in younger diabetic patients (aged 25 to 45 years) with a duration of diabetes between 1-5 years (newly diagnosed with diabetes). The other reasons include lack of awareness 16.05% and lack of financial resources 17.28%. Lack of financial resources is the least cause of medication non-adherence in diabetic patients in India. Patients with medication non-adherence are associated with an increased risk of developing diabetic complications which further decreases their quality of life.

The Mean EQ Index score was found to be 0.85 which is similar to the study results conducted by Solli *et al.*⁽³⁸⁾ and comparable to the study results reported by UKPDS 37⁽³³⁾(0.83) and Parikh *et al.*⁽²⁵⁾ (0.803). The Mean EQ VAS score was found 78.25 which is similar to the studies conducted by Parikh *et al.*⁽²⁵⁾ In our study, the EQ VAS scores are higher in males than in females which are related to the study findings reported by Solli *et al.*⁽³⁸⁾ and Javanbakht *et al.*⁽³⁹⁾ whereas studies conducted by Parikh *et al.* and D'Souza *et al.*⁽⁴⁰⁾ reported contrasting results in which females scored higher EQ VAS than men. A significant negative correlation was observed between the trends of the EQ Index and EQ VAS scores and the presence of complications among the patients. The highest EQ Index (0.9206) and EQ VAS scores (86.88) were found in patients with no complications and the mean scores are observed in a decreasing fashion with the increasing number of complications. Both the EQ Index and EQ VAS scores were found significantly lower in the patients with uncontrolled type 2 diabetes than in the controlled group which is similar to several studies which stated that comorbidities have an adverse influence on HRQoL of patients with type 2 diabetes mellitus.^(41,42)

Conclusion

Our study found that patients with type 2 diabetes mellitus have poor health-related quality of life. Non-adherence to medication and the presence of diabetic complications further deteriorate the quality of life of the patients. Promoting strict adherence to medication and effective treatment of the complications at an early stage can reduce the worsening of the disease and diabetic complications thereby improving the patient's quality of life.

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